IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 23-866-UNA
	:	
ZYDUS PHARMACEUTICALS (USA), INC., et al.,	:	
	:	
Defendants.	:	

ORDER

The motion for a TRO (D.I. 4) is **DENIED**.

According to Plaintiffs, non-Defendant Apotex has been on the market with a generic since January 2023, and has a 20% market share. (D.I. 6 at 6-7). The market entry by Apotex caused the "average net selling price" of Plaintiffs' product to drop from $198 per unit to $144 per unit. (*Id.* at 7). According to Plaintiffs, Defendants began shipping generic products on June 27, 2023. (*Id.*). This has led to a further drop from $144 to $111 per unit. (*Id.*). Plaintiffs expect further price erosion.

Six weeks have passed since Defendants entered the market.[1] The PTO issued the only asserted patent (the '524 patent) yesterday. (D.I. 8-1, Ex. 1).[2] The '524 patent has 30 method

[1] It appears that Plaintiffs have expected Defendants' market entry since at least June 13, 2023, when Defendants announced FDA approval of their generic. (D.I. 8-1, Ex. 6). Indeed, Plaintiffs contacted Defendants about this matter a month before that, on May 17, 2023. (*Id.*, Ex. 4).

[2] The application for the '524 patent was filed on September 9, 2022.

claims for making a "varenicline tartrate tablet" or "varenicline tartrate." (D.I. 7, p. 8). It seems likely that Defendants' varenicline tartrate generic is being manufactured abroad.

Plaintiffs' expert states that there is a "possibility" that Defendants are infringing the claims. (D.I. 7, p. 11). In their brief, Plaintiffs describe the infringement as "suspected." (D.I. 5 at 6).

Plaintiffs essentially concede that they do not know whether Defendants are making the generic product using a process protected by the '524 patent. Instead, they assert that Defendants have the burden of proving they do not infringe, citing 35 U.S.C. § 295. I do not understand that statute to be a basis for issuing a TRO, and I do not see any cases cited by Plaintiffs that have involved that statute and TROs (or, for that matter, a preliminary injunction). I think that statute, if it applies, would apply at a trial. I do not think it is plausible that it applies to a motion filed one day after Plaintiffs obtained a patent. I note in part its rationale that it "serves the needs of the court as a mechanism for enforcing its processes and orders." *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. ITC*, 224 F.3d 1356, 1360 (Fed. Cir. 2000). In most cases, it never comes into play because defendants comply with relevant discovery orders and there is therefore no need to shift burdens. I also note that district courts have discretion as to when to invoke § 295. *Id.* The day after the patent issues does not appear to be the time to be doing that.

Under the circumstances as I understand them, therefore, Plaintiffs have not shown a likelihood of success on the merits.

There is no basis for the issuance of a TRO.

Plaintiffs seek to file their opening brief under seal. (D.I. 3). I grant that, but with the warning to Plaintiffs that if they over-redact the brief, I will summarily unseal it. I note, in

particular, if they want to force Defendants to withdraw from the market on the basis of irreparable financial harm, the claims to such harm should be public.

Plaintiffs seek a preliminary injunction and expedited discovery. (D.I. 4). There is no need to set a date for a preliminary injunction, or to order expedited discovery, *ex parte*.

I refer this matter to Magistrate Judge Hatcher to set and manage a schedule for expedited discovery and to advise when it would be appropriate to schedule a hearing on the motion for a preliminary injunction.

IT IS SO ORDERED this 9th day of August 2023.

United States District Judge